

REMARKS

Claims 112-224 were pending in the application. Claims 112, 149, 182, 222 and 224 have been amended and claims 119, 121-122, 125-126, 128-130, 135-136, 140, 146, 154-156, 159-160, 162-164, 169-170, 174, 179, 191, 193-195, 198-199, 201-203, 208-209, 213 and 218 have been cancelled as being directed to a non-elected invention. Accordingly, when the amendments presented herein have been entered, claims 112-118, 120, 123-124, 127, 131-134, 137-139, 141-145, 147-153, 157-158, 161, 165-168, 171-173, 175-178, 180-190, 192, 196-197, 200, 204-207, 210-212, 214-217, and 219-224 will be pending. No new matter has been added.

Applicants reserve the right to pursue the cancelled claims and the claims as originally filed in one or more continuing applications.

Rejection of Claims 112-118, 120, 123-124, 127, 131-134, 137-139, 141-145, 147-148, 182-190, 192, 196-197, 200, 204-207, 210-212, 214-217, and 219-224 Under 35 USC 112, First Paragraph

The Examiner has rejected claims 112-118, 120, 123-124, 127, 131-134, 137-139, 141-145, 147-148, 182-190, 192, 196-197, 200, 204-207, 210-212, 214-217, and 219-224 under 35 USC 112, first paragraph as failing to comply with the written description requirement.

Referring to steps (b) and (e) of claims 112 and 182, the Examiner states that “the specification does not provide support for the limitation ‘a classification *is* a function of a data element value;’ it is only disclosed that the classification models are used for quantification wherein the models recognize patterns derived from data elements.”

While in no way acquiescing to the validity of the Examiner’s rejection, and solely in the interest of expediting prosecution, Applicants have amended claims 112 and 118 to better describe the claimed subject matter.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

Rejection of Claims 112-118, 120, 123-124, 127, 131-134, 137-139, 141-145, 147-153, 157-158, 161, 165-168, 171-173, 175-178, 180-190, 192, 196-197, 200, 204-207, 210-212, 214-217, and 219-224 Under 35 USC 112, Second Paragraph

The Examiner has rejected claims 112-118, 120, 123-124, 127, 131-134, 137-139, 141-145, 147-153, 157-158, 161, 165-168, 171-173, 175-178, 180-190, 192, 196-197, 200, 204-207, 210-212, 214-217, and 219-224 under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner indicates that the phrase “the first samples and the second samples” in claim 112 step (d) substep (iii) is unclear.

While in no way acquiescing to the validity of the Examiner’s rejection, and solely in the interest of expediting prosecution, Applicants have amended claim 112 so as to clarify the subject matter being claimed.

Rejection of Claim 112, 149 and 182 Under 35 USC 112, Second paragraph

The Examiner has rejected claims 112, 149 and 182 under 35 USC 112, second paragraph as being unclear. Specifically, the Examiner believes that the claim element “wherein classification is a function of a data element value” is unclear. While in no way acquiescing to the validity of the Examiner’s rejection, and solely in the interest of expediting prosecution, Applicants have amended claims 112 and 182 so as to clarify the subject matter being claimed.

Rejection of Claims Under 35 USC 103(a)

The Examiner has rejected claims 112-117, 123-124, 127, 131-134, 137-139, 141, 143-145, 147-148, and 221-224 under 35 U.S.C. §103(a) as being unpatentable over Petricoin in view of Golub, Science, 286:531-537 (“Golub”).

The Examiner has also rejected claims 118, 120, 142, 149-153, 157-158, 161, 165-168, 171-173, 175-178, 181-190, 192, 196-197, 200, 204-207, 210-212, 214-217 and 219-220 under 35 U.S.C. under 35 U.S.C. §103(a) as being unpatentable over Petricoin in view of Barnhill, U.S. Patent No. 6,789,069.

For the sake of brevity, the two rejections under 103(a) are addressed together because each rejection relies on the Petricoin in combination with a secondary reference.

Applicants respectfully traverse these two rejections.

Applicant's claims call for performing multivariate analysis on a first set of samples that includes samples classified into at least two different biological states (e.g., cancer and non-cancer) and, separately, performing multivariate analysis on a second set of samples that includes samples classified into the different biological states.

The method further requires the selection of first and second subsets of qualified common data elements from the first and second data sets, respectively, and further selecting an intersection subset of data elements from these two subsets.

Nowhere does Petricoin suggest such methods as Applicants claim, including the selection of an intersection subset.

Independent claims 149 and 182 also call for first and second independent discovery data sets.

Applicants have found their disclosed preferred methods can provide notable advantages, including accurate identification of desired biomarkers. This is discussed at page 3, first paragraph of the present application:

The invention provides bioinformatics tools to analyze expression profiling data of samples from two or more independent sources in a way which reduces the sources of variability and biases which result in identification of false targets during the drug discovery process. In contrast to prior methods, data from multiple sources are NOT pooled together in a combined data set and then divided into a discovery-training set and a test-validation set. Instead, data from multiple sources (e.g., such as multiple different clinical trial sites) are analyzed separately and independently from the others. For each source, sufficient sample size and statistical re-sampling methods (e.g., such as bootstrap analysis) help to discover biomarkers that perform well in a representative population and perform *consistently* well among different randomly selected subpopulations.

Nor does Petricoin or any of the other cited documents disclose or suggest: use of an intersection subset of data elements as Applicants disclose and claim, i.e.

“selecting an intersection subset of data elements from the first and second subsets, wherein each data element in the intersection subset is a member of both of the first and second subsets” as recited in Applicants’ independent claim 112;

“a third computer readable program providing instructions for selecting an intersection subset of data elements from the initial subsets, wherein each data element in the intersection subset is a member of a majority of the initial subsets” as recited in Applicants’ independent claim 149; and

“executing computer readable program code providing instructions for selecting an intersection subset of data elements from the initial subsets, wherein each data element in the intersection subset is a member of a majority of the initial subsets” as recited in Applicants’ independent claim 182.

Golub fails to remedy such deficiencies of the Petricoin document. Golub merely reports that prediction strength was low from laboratories using different collection protocols, see p. 533, first column. Notably, Golub also reports that sample preparations should be standardized, thereby teaching away from Applicants’ method where independent discovery data sets may be collected from different locations or from using different collection protocols. Nowhere does Golub disclose or suggest “selecting an intersection subset of data elements from the first and second subsets” as Applicants claim.

Barnhill also does not disclose or suggest use of first and second independent discovery data sets as Applicants claim. Barnhill also does not suggest “selecting an intersection subset of data elements from the first and second subsets” as Applicants claim.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejections.

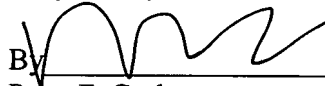
CONCLUSION

In view of the above amendment and response, Applicants believe that the pending application is in condition for allowance.

A request for a three month extension of time is enclosed. The Director is hereby authorized to charge any credits or deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 58369 (71699).

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Respectfully submitted,

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